110TH CONGRESS
2D SESSION

H. R. 7199

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2008

Mr. CANNON introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Information and Treatment Access Act".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. FINDINGS.

The Congress finds as follows:

(1) The Congress and the American people desire to live healthy lives and foster an effective and efficient health care system. This system requires timely, accurate, and ever-improving information resources. This will foster maximization of health care outcomes and help health care practitioners and patients partner for more effective results.

(2) The Internet is a unique tool offering access to great volumes of information. Some is accurate and some is not. There has also been extensive government investment in placing medical information on the Internet in many diverse places.

(3) There is a need to consolidate and translate this myriad of information for physicians and consumers, from the listing of clinical trials to the pro-

tocols for treatment of various diseases and conditions, as well as the integration of new discoveries and the evaluations of outcomes-based examinations of drugs and devices for conditions other than those for which they are already approved. This will lead to more accurate treatment, fewer medical errors, and more successful outcomes, while also protecting patients, a physician's right to practice medicine, and a patient's right to access the health care the patient desires.

(4) The Food and Drug Administration is uniquely qualified to assist the Nation in fulfilling this mission to improve health care for the benefit of Americans. The Administration already coordinates the information needs of many government agencies and equivalent regulatory bodies in other countries.

(5) In providing Internet-based forums for obtaining and disseminating health-related information (including information on surgical procedures; complimentary and alternative medicine; dietary supplements and food; and unapproved treatments), the Food and Drug Administration should work closely with educational institutions, schools of medicine, and other appropriate private entities and ensure

that the expertise of such entities is appropriately utilized.

TITLE I—FEDERAL INTERNET SITE FOR CONSOLIDATION AND TRANSLATION OF INFORMATION ON DISEASES AND OTHER CONDITIONS

SEC. 101. INTERNET SITE.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall carry out a program whose mission is, through an Internet site maintained for purposes of the program—

(1) to consolidate and translate health care information that is available to the public from Federal agencies, linking the various health-related Internet sites of such agencies; and

(2) to assist in the translation and reporting of disease or condition protocols for physicians and lay persons.

(b) INFORMATION ON DISEASES AND OTHER CONDITIONS.—The Secretary shall ensure that the Internet site under subsection (a) has capacities that enable a user of the site to enter the name of a disease or other health condition and obtain Internet links appropriate to health

care providers, and links appropriate to lay persons, that provide—

(1) an explanation of the health condition; and

(2) information on all available treatment protocols, including—

(A) standard medical practice protocols; and

(B) any clinical trials, and any outcomes-based treatment protocols, that—

(i) are being conducted or supported by the National Institutes of Health;

(ii) are included in the registry and results data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j));

(iii) are being conducted pursuant to the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(iv) are being conducted pursuant to section 201 of this Act; or

(v) are identified pursuant to section 201 or 202 of this Act or pursuant to section 485D(i) of the Public Health Service Act (as added by section 203 of this Act).

(c) FEDERAL DATABASES.—Internet links under subsection (b) shall include the following:

(1) Links that provide information on how to enroll in a clinical trial referred to in subsection (b)(2)(B) and how to be treated under an outcomes-based treatment protocol referred to in such subsection.

(2) Links to Federal electronic databases that are available to the public and provide disease-specific or condition-specific information, including such databases of the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(3) A link to the Internet site under section 204(a) (relating to research and treatments carried out pursuant to section 201, and the identity of the health care practitioners involved).

(4) A link to the Internet sites under sections 201 and 202 of this Act and the Internet site under section 485D(i) of the Public Health Service Act (as added by section 203 of this Act).

(d) DATE CERTAIN FOR OPERATION OF PROGRAM.—The Internet site under subsection (a) shall be established and ready for use by health care practitioners and lay per-

sons not later than two years after the date of the enactment of this Act.

TITLE II—ADDITIONAL FORUMS FOR EXCHANGE OF HEALTH INFORMATION

SEC. 201. FORUM REGARDING OFF-LABEL USES OF NEW DRUGS AND DEVICES.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall (directly or through contract) establish a program under which the following occur:

(1) Health care practitioners submit to the Secretary information obtained in the course of their professional practices regarding off-label uses of new drugs and devices.

(2) The Secretary maintains the information received under paragraph (1); makes such information available to health care practitioners and the general public through one or more Internet sites; and receives, maintains, and makes available through such site appropriate comments and information provided in response to such information.

(3) The Secretary carries out paragraph (2) in a manner reasonably calculated to provide a forum

for obtaining and disseminating information, including clinical data, toward the following goals:

(A) Identifying off-label uses of new drugs and devices that are reasonable candidates for approval under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act or under section 351 of the Public Health Service Act.

(B) Identifying off-label uses of new drugs and devices that constitute a threat to the public health.

(C) Making available to the Secretary information for uses with respect to promoting innovations in evidence-based clinical practice and health care technologies under title IX of the Public Health Service Act.

(b) VOLUNTARY PARTICIPATION.—Subsection (a) may not be construed as requiring that any health care practitioner or other person participate in the program under such subsection.

(c) CERTAIN AUTHORITIES.—The posting by the Secretary of information on an Internet site under subsection (a) is subject to the following:

(1) The Secretary may not post information submitted by a health care practitioner unless the practitioner authorizes the Secretary to include in

the posting the identity and the business address of the practitioner.

(2) The Secretary may impose reasonable restrictions on the format and volume of information to be posted and on the frequency of postings.

(d) CRITERIA.—Not later than one year after the date of the enactment of this Act, the Secretary shall by regulation issue criteria for carrying out this section.

SEC. 202. JOHN EISENBERG FORUM REGARDING SURGICAL PROCEDURES.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall (directly or through contract) establish a program under which the following occur:

(1) Health care practitioners submit to the Secretary information obtained in the course of their professional practices regarding surgical procedures.

(2) The Secretary maintains the information received under paragraph (1); makes such information available to health care practitioners and the general public through one or more Internet sites; and receives, maintains, and makes available through such site appropriate comments and information provided in response to such information.

(3) The Secretary carries out paragraph (2) in a manner reasonably calculated to provide a forum for obtaining and disseminating information, including clinical data, toward the following goals:

(A) Identifying innovative surgical procedures.

(B) Identifying surgical procedures that constitute a threat to the public health.

(C) Making available to the Secretary information for uses with respect to promoting innovations in evidence-based clinical practice and health care technologies under title IX of the Public Health Service Act.

(b) VOLUNTARY PARTICIPATION.—Subsection (a) may not be construed as requiring that any health care practitioner or other person participate in the program under such subsection.

(c) CERTAIN AUTHORITIES.—The posting by the Secretary of information on an Internet site under subsection (a) is subject to the following:

(1) The Secretary may not post information submitted by a health care practitioner unless the practitioner authorizes the Secretary to include in the posting the identity and the business address of the practitioner.

(2) The Secretary may impose reasonable restrictions on the format and volume of information to be posted and on the frequency of postings.

(d) CRITERIA.—Not later than one year after the date of the enactment of this Act, the Secretary shall by regulation issue criteria for carrying out this section.

SEC. 203. JOHN EISENBERG FORUM REGARDING COMPLEMENTARY AND ALTERNATIVE MEDICINE; DIETARY SUPPLEMENTS AND FOOD.

Section 485D of the Public Health Service Act is amended—

(1) by redesignating subsections (i) and (j) as subsections (j) and (k), respectively; and

(2) by adding after subsection (h) the following subsection:

"(i) JOHN EISENBERG FORUM FOR EXCHANGE OF INFORMATION.—

"(1) IN GENERAL.—The Director of the Center, in consultation with the Commissioner of Food and Drugs, shall (directly or through contract) establish a program under which the following occur:

"(A) Health care practitioners submit to the Director information obtained in the course of their professional practices regarding complementary and alternative treatment, diag-

nostic and prevention modalities, disciplines and systems.

"(B) The Director maintains the information received under subparagraph (A); makes such information available to health care practitioners and the general public through establishing one or more Internet sites; and receives, maintains, and makes available through such site appropriate comments and information provided in response to such information.

"(C) The Director carries out subparagraph (B) in a manner reasonably calculated to provide a forum for obtaining and disseminating information, including clinical data, toward the following goals:

"(i) Identifying alternative treatment, diagnostic and prevention systems, modalities, and disciplines that should be integrated with the practice of conventional medicine as a complement to such medicine and integrated into health care delivery systems in the United States.

"(ii) Identifying any alternative medical practices or procedures that constitute a threat to the public health.

"(iii) Making available to the Commissioner of Food and Drugs information for uses with respect to promoting innovations in evidence-based clinical practice and health care technologies under title IX of the Public Health Service Act.

"(2) DIETARY SUPPLEMENTS AND FOOD.—In consultation with the Commissioner of Food and Drugs, the Director of the Center shall carry out the following:

"(A) Activities under paragraph (1) shall include carrying out such paragraph with respect to information that relates to the effects of dietary supplements and food on diseases and disorders and is obtained by the practitioners in the course of their professional practices and submitted to the Director.

"(B) With respect to paragraph (1)(C) as applied for purposes of this paragraph, the goals shall be the following:

"(i) Identifying dietary supplements and food and uses of such supplements and food that are of clinical benefit in treating particular diseases or disorders.

"(ii) As appropriate, providing for the publication of authoritative statements, within the meaning of section 403(r)(3)(C)(i) of the Federal Food, Drug, and Cosmetic Act, about the relationship between a nutrient and a disease or health-related condition.

"(iii) Carrying out paragraph (1)(C)(iii) with respect to dietary supplements.

"(3) VOLUNTARY PARTICIPATION.—Paragraph (1) may not be construed as requiring that any health care practitioner or other person participate in the program under such paragraph.

"(4) CERTAIN AUTHORITIES.—The posting by the Director of the Center of information on the Internet site under paragraph (1) is subject to the following:

"(A) The Director may not post information submitted by a health care practitioner unless the practitioner authorizes the Director to include in the posting the identity and the business address of the practitioner.

"(B) The Director may impose reasonable restrictions on the format and volume of infor-

mation to be posted and on the frequency of postings.

"(5) CRITERIA.—Not later than one year after the date of the enactment of the Medical Information and Treatment Access Act, the Secretary shall by regulation issue criteria for carrying out this subsection.

"(6) DEFINITIONS.—For purposes of this subsection, the terms 'dietary supplement' and 'food' have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.".

TITLE III—GENERAL PROVISIONS

SEC. 301. DEFINITIONS.

For purposes of this Act:

(1) The terms "device", "labeling", and "new drug" have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301).

(2) The term "off-label use", with respect to a new drug or a device, means a use not included in the labeling approved for the drug or device pursuant to section 505, 510, or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360e,

360e) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(3) The term "Secretary" means the Secretary of Health and Human Services.

SEC. 302. EFFECTIVE DATES.

(a) IN GENERAL.—Subject to subsection (b)—

(1) sections 201 and 202 take effect on the date on which a final rule takes effect pursuant to sections 201(d) and 202(d), respectively; and

(2) the amendment made by section 203 takes effect on the date on which the final rule required under section 485D(i)(5) of the Public Health Service Act (as added by such amendment) takes effect.

(b) ISSUANCE OF CRITERIA.—Sections 201(d) and 202(d) of this Act and section 485D(i)(5) of the Public Health Service Act (as added by section 203 of this Act) take effect on the date of the enactment of this Act.

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